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Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals

Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals

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Item 4 (b) of the provisional agenda
Hazard communication:
Improvement of annexes 1 to 3 and further rationalization of precautionary statements

Proposed changes to Annex 3 of the GHS to improve medical response precautionary statements (P310 to P315)

Transmitted by the expert from the United Kingdom on behalf of the informal working group on improving annexes 1, 2 and 3 of the GHS*

Background

1. In line with its mandate for the 2017-2018 biennium the informal working group has taken forward work under its Workstream 1: "to develop proposals to rationalise and improve the comprehensibility of hazard and precautionary statements for users, while taking into account usability for labelling practitioners. This may include proposals to rationalise and clarify ambiguous or unhelpful instructional precautionary statements (PS), such as statements relating to medical response and disposal."

2. This document presents the outcome of work on item 1 in the Group's workplan (UN/SCEGHS/32/INF.12/Rev.1) where the issue is summarised as: "The precise meaning of the medical response statements (P310-P315) is not clear and manufacturers/suppliers

* In accordance with the programme of work of the Sub-Committee for 2017–2018 approved by the Committee at its eighth session (see ST/SG/AC.10/C.3/100, para. 98 and ST/SG/AC.10/44, para. 14).

have encountered difficulties in choosing the appropriate wording from the two options. Translation of the Precautionary Statement and conditions for use has also resulted in discrepancies.".

3. Specific issues arising from the existing medical response PS include:

- There are too many;
- Providing options using a forward slash "/" or three dots "…" has not been successful, as often no choice is made and these notations appear on labels;
- Access to poison centres (where they exist) varies in different jurisdictions. In some jurisdictions access is restricted to medical staff only whilst in others they are also available to the general public;
- Although "medical advice" and "medical attention" can be distinguished[1], in practice the distinction is subtle and not always helpful in providing clear messages for medical response in the event of an incident. Furthermore, translation of these terms into other languages can be problematic[2].

Discussion

Medical response precautionary statements

4. In undertaking its work on medical response statements, the informal working group decided to start with a blank sheet and adopted the following general principles:

- Keep it simple;
- Look at a simple matrix of urgency versus seriousness, and consider possible medical response for the four possible combinations of high and low (High High (HH); High Low (HL); Low High (LH); and Low Low (LL));
- Focus high urgency/high seriousness (HH) response on situations where immediate medical help is needed (acute high hazard), i.e. potentially life-threatening situations;
- To keep it simple, use the same medical response statement for hazard classes/categories within the three other quadrants (HL, LH and LL) if possible;
- Consider the following qualifiers for low urgency situations, where approporiate: **if you feel unwell**, or **if exposed or concerned**;
- Avoid choices or additions for suppliers by not using '/' or '…' (c.f. Poison Centre/doctor/…), where possible;
- Aim for simple, succinct, translatable and universally understood PS, applicable in all jurisdictions that distinguish the hazard classes and categories requiring immediate/urgent medical help from those requiring less urgent medical help.

5. Figure 1 below brings together the informal working group's considerations for the new medical response PS and the proposed allocation of the hazard classes and categories.

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[1] Informal document INF.13 (thirty-second session) – "Medical advice and medical attention".

[2] Document ST/SG/AC.10/C.4/2016/20 – "Precautionary statements on medical advice/attention: correction of linguistic discrepancies".

6. The Sub-Committee may wish to note that work to ensure correct allocation of hazard sub-categories in Annexes 1, 2 and 3 is addressed in a separate working document (ST/SG/SC.10/C.4/2018/6). The notation in this paper on medical response PS is based on GHS revision 7.

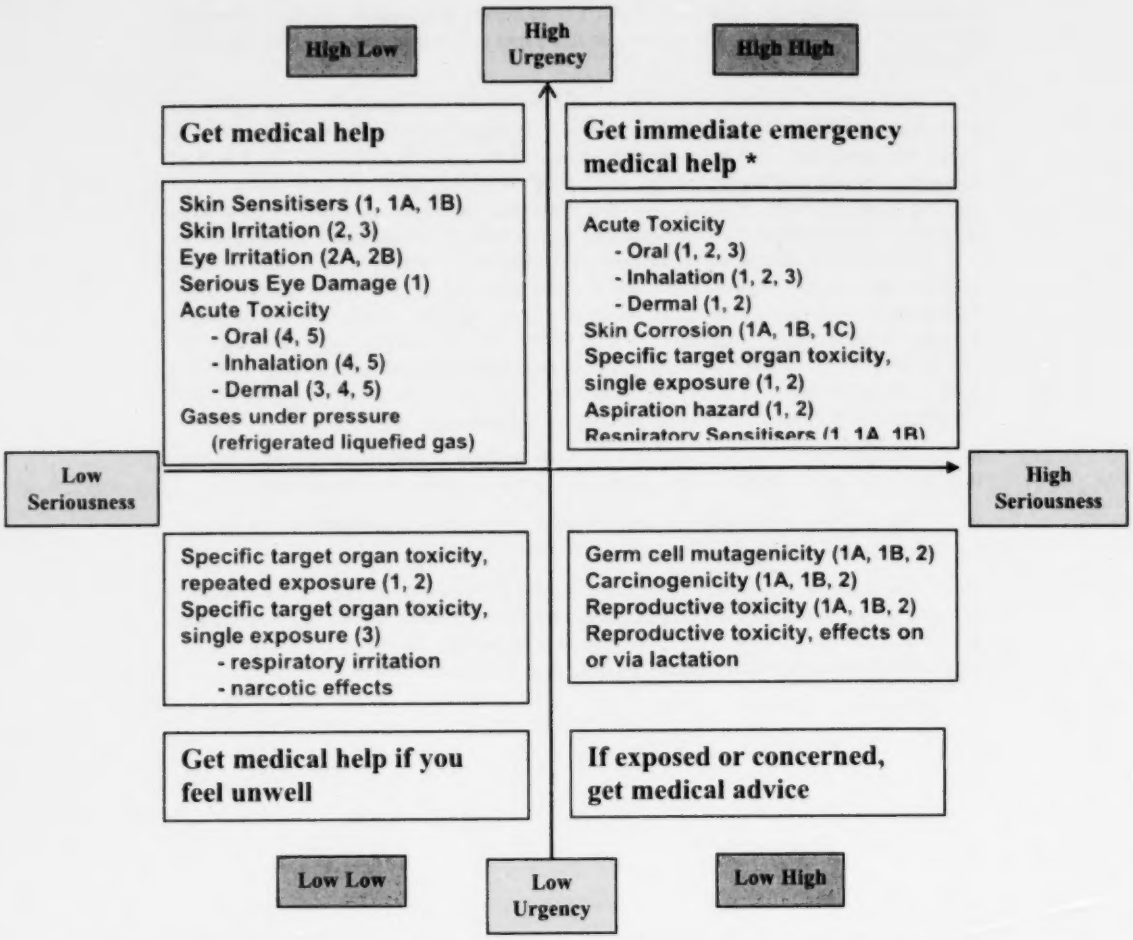
7. The informal working group agreed that the PS for the chemicals in hazard classes and categories allocated in the HH quadrant, i.e. potentially life-threatening, should clearly signal the need for emergency medical help. For many jurisdictions the PS "**Get immediate emergency medical help**" will be sufficient. A challenge was to find a way to indicate more precisely what to do in the emergency situation where this is considered necessary. Noting that in the past providing options using a forward slash "/" or three dots "…" has not been successful in the context of medical response, the informal working group proposes a new approach in Column 5 to permit the use of additional information. This enables the competent authority or manufacturer / supplier to add 'Call', followed by the appropriate emergency telephone number for the country or region concerned (e.g. 911, 111 or 999), or by the appropriate provider of emergency medical help, which could be a poison centre, emergency centre, doctor or alternative, in line with the arrangements and organisation of the health services in the country or region concerned.

8. To help ensure that the emergency response services worldwide are focussed where they are most needed, this additional information is applicable to the HH quadrant only.

9. The informal working group is not aware of any significant problems in translating the four proposed PS for medical response into other languages.

10. Consistent with the current approach, the new PS would always follow the relevant **IF…** PS (P301-P306), sometimes in conjunction with one or more specific actions. Some examples of possible combination statements with the new PS for medical response that suppliers could use in practice are in Part I of informal document INF.8.

Figure 1


High Low
High Urgency
High High
Get medical help
Skin Sensitisers (1, 1A, 1B)
Skin Irritation (2, 3)
Eye Irritation (2A, 2B)
Serious Eye Damage (1)
Acute Toxicity
- Oral (4, 5)
- Inhalation (4, 5)
- Dermal (3, 4, 5)
Gases under pressure
(refrigerated liquefied gas)
Get immediate emergency medical help *
Acute Toxicity
- Oral (1, 2, 3)
- Inhalation (1, 2, 3)
- Dermal (1, 2)
Skin Corrosion (1A, 1B, 1C)
Specific target organ toxicity, single exposure (1, 2)
Aspiration hazard (1, 2)
Low Seriousness
High Seriousness
Specific target organ toxicity, repeated exposure (1, 2)
Specific target organ toxicity, single exposure (3)
- respiratory irritation
- narcotic effects
Germ cell mutagenicity (1A, 1B, 2)
Carcinogenicity (1A, 1B, 2)
Reproductive toxicity (1A, 1B, 2)
Reproductive toxicity, effects on or via lactation
Get medical help if you feel unwell
If exposed or concerned, get medical advice
Low Low
Low Urgency
Low High

* Competent Authority or manufacturer / supplier may add "Call" followed by the appropriate emergency telephone number, or the appropriate emergency medical help provider, for example, a poison centre, emergency centre or doctor.

11. The proposed new PS with the hazard classes/categories to which they are assigned are also shown in Table 1 below. The advantages of the proposed PS compared to the existing P310 to P315 are:

(a) The number of medical response PS is reduced from 6 to 4.

(b) The action to take is conveyed more clearly and the potential confusion between 'medical advice' and medical attention' is avoided.

(c) The new PS don't use "/" or "…" and so manufacturers and suppliers don't have to make difficult choices between options.

Where immediate medical help is needed provision has been made to allow competent authorities or manufacturers / suppliers to add additional information specifying the appropriate number to call or the emergency provider to contact.

12. In considering the new medical response PS the informal working group agreed that in the event of accidental exposure to substances and mixtures classified as gases under pressure (refrigerated liquefied gas) or serious eye damage the situation would not generally be potentially life-threatening, and the appropriate response was **"Get medical help"** rather than **"Get immediate emergency medical help"**.

Presentation of the new medical response precautionary statements

13. In line with advice from the secretariat, to avoid confusion between the existing medical response PS (P310 to P315) in versions of the GHS up to and including the seventh revised edition, it is proposed to delete the current codes P310 to P315 and assign new codes P316 to P319 to the four proposed new medical response PS. For clarity "deleted" is inserted into column 1 of Table A3.2.3 beneath the codes that become obsolete. In addition, some explanatory text is inserted in Annex 3, section 2 (see Part II of informal document INF.8).

Further changes and rationalisation of precautionary statements

14. In the proposed new PS for medical response the existing P308, "**If exposed or concerned:"** is incorporated in P318 "**If exposed or concerned get medical advice**" in a similar way to "… **if you feel unwell"** (now part of P314). The proposed new PS P318 is applied to the hazard classes carcinogenic, mutagenic and reprotoxic (CMRs) in line with P308 now. However, P308 is also currently applied to substances or mixtures classified as specific target organ toxicity, single exposure (STOT SE) (1, 2). The informal working group considered that in these cases "**Get immediate emergency medical help"** is the appropriate medical response. As the routes of exposure for classification as STOT SE (1, 2) are often not known or available, P308 is retained for this hazard class and categories. However, P308+P313, which applies only to CMRs, can be deleted.

15. P308 is also needed to retain the existing provision to replace three or more routes of exposure (P301 to 306) in combination with the same medical response statement with **"IF exposed or concerned:"**.

16. P302 and P303 are also rationalised by deleting P303, "**IF ON SKIN (or hair)**", and using instead P302, "**IF ON SKIN"**. The hazard classes and categories currently allocated to P303 (Flammable liquids (1 - 3) and Skin corrosion (1A, 1B, 1C)) are added to P302. It was considered that skin includes hair, and the distinction between P302 and P303 is not meaningful or helpful in practice.

Proposal

17. Table 1 below sets out the proposed new PS for medical response.

18. Other changes in the proposal are to:

(a) Make the conforming changes in Table A3.2.3 to combination PS including medical response to reflect Table 1;

(b) Delete the response precautionary statements, hazard classes, hazard categories and associated column 5 entries for the following PS from Table A3.2.3,

and insert "**deleted**" in column 1 below each of the codes: P303, P310, P311, P312, P313, P314, P315;

(c) Delete the following combined PS entry from Table A3.2.3: P308 + P313;

(d) Delete the hazard classes / categories for carcinogenic, mutagenic and reprotoxic (CMRs) as listed under P308 in Table A3.2.3;

(e) Move the hazard classes / categories for flammable liquids (1, 2, 3) and skin corrosion (1A, 1B, 1C) as listed under P303 to P302 in Table A3.2.3, and delete P303;

(f) Make the conforming changes to combination PS including P30;

(g) Amend A3.2.3.5 of Annex 3, section 2 to cover provision of additional information as appropriate (new text underlined):

"A3.2.3.5 In cases where additional information is required, or information either has to be or may be specified, this is indicated by a relevant entry in column (5) in plain text."

(h) Insert a new paragraph A.3.2.3.9 in Annex 3, Section 2 on deleted codes:

"A3.2.3.9 Where precautionary statements become obsolete, "**deleted**" is inserted under the existing code in column 1 of the tables in this Section to avoid potential confusion between codes used in different editions of the GHS."

(i) Replace A3.3.2.4 in Annex 3, Section 3, "Application of precautionary statements concerning medical response" with the corresponding text in Part II of informal document INF.8;

(j) Make the necessary conforming amendments to the matrix of PS by hazard class/category in Annex 3, Section 3.

19. Part II of informal document INF.8 sets outs the changes in full. New text is shown in red. Deleted text is shown in ~~strikethrough~~.

Action requested

20. The Sub-Committee is invited to agree to the proposed changes to Annex 3, sections 2 and 3 as set out in paragraphs 17 to 18 above and Part II of informal document INF.8.

Table 1

Code (1)	Response precautionary statements (2)	Hazard class (3)	Hazard category (4)	Conditions for use (5)
P316	**Get immediate emergency medical help.**	Acute toxicity, oral (chapter 3.1)	1, 2, 3	Competent Authority or manufacturer / supplier may add, 'Call' followed by the appropriate emergency telephone number, or the appropriate emergency medical help provider, for example, a Poison Centre, Emergency Centre or Doctor.
		Acute toxicity, dermal (chapter 3.1)	1, 2	
		Acute toxicity, inhalation (chapter 3.1)	1, 2, 3	
		Skin corrosion (chapter 3.2)	1A, 1B, 1C	
		Respiratory sensitization (chapter 3.4)	1, 1A, 1B	
		Specific target organ toxicity, single exposure, (chapter 3.8)	1, 2	
		Aspiration hazard (chapter 3.10)	1, 2	
P317	**Get medical help.**	Gases under pressure (chapter 2.5)	Refrigerated liquefied gas	
		Acute toxicity, oral (chapter 3.1)	4, 5	
		Acute toxicity, dermal (chapter 3.1)	3, 4, 5	
		Acute toxicity, inhalation (chapter 3.1)	4, 5	
		Skin irritation (chapter 3.2)	2, 3	
		Serious eye damage (chapter 3.3)	1	
		Eye irritation (chapter 3.3)	2A, 2B	
		Skin sensitization (chapter 3.4)	1, 1A, 1B	
P318	**If exposed or concerned, get medical advice.**	Germ cell mutagenicity (chapter 3.5)	1A, 1B, 2	
		Carcinogenicity (chapter 3.6)	1A, 1B, 2	
		Reproductive toxicity (chapter 3.7)	1A, 1B, 2	
		Reproductive toxicity, effects on or via lactation (chapter 3.7)	Additional category	
P319	**Get medical help if you feel unwell.**	Specific target organ toxicity, single exposure, respiratory tract irritation (chapter 3.8)	3	
		Specific target organ toxicity, single exposure, narcotic effects (chapter 3.8)	3	
		Specific target organ toxicity, repeated exposure (chapter 3.9)	1, 2	